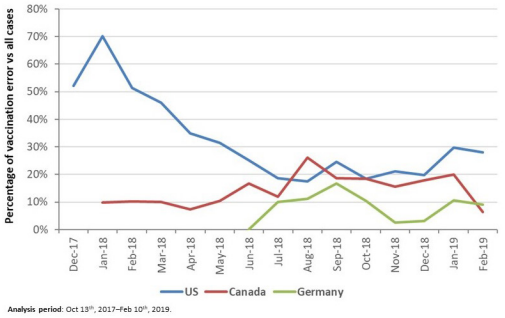
Table 1. Most commonly reported* sign/symptoms events involving RZV vaccination

Sign/Symptoms**	Reporting rate***
Injection-site pain	18.2
Pyrexia	17.8
Pain in extremity	15.7
Pain	14.2
Chills	13.3
Injection-site erythema	13.1
Fatigue	11.6
Headache	11.5
Influenza like illness	9.3
Herpes zoster	9.0
Myalgia	8.6
Injection-site swelling	8.4
Erythema	7.0
Malaise	6.9
Nausea	6.0
Rash	5.8
Injection-site warmth	4.3
Pruritus	3.4
Arthralgia	3.3
Peripheral swelling	3.2
Asthenia	2.6
Dizziness	2.6
Swelling	2.6
Injection-site pruritus	2.5
Feeling abnormal	2.4
Injection-site rash	2.2

Analysis period: Oct 13th, 2017–Feb 10th, 2019. *Only adverse events with a reporting rate >2.0 per 100,000 distributed doses are shown. Vaccination errors were not included in the list. **Based on Medical Dictionary for Regulatory Activities (MedDRA, version 21.1) preferred term; a single report may contain more than 1 MedDRA preferred term. ***Reports per 100,000 RZV doses distributed worldwide during the analytic period.

Figure 2. Evolution of the percentage of vaccination error reports versus all reports with RZV, by country



Analysis period: Oct 13th, 2017–Feb 10th, 2019.

Table 2. Number (%) of reports* of vaccination errors involving RZV

Vaccination error group** (description)	Number (%) of reports* (N=3,579)
Product preparation/reconstitution errors	1,062 (29.7)
Inappropriate/incomplete course of administration	956 (26.7)
Incorrect route of administration	585 (16.4)
Product storage error	463 (12.9)
Other errors	513 (14.3)

Analysis period: Oct 13th, 2017–Feb 10th, 2019. *A report may describe more than 1 error. **A group contains multiple MedDRA preferred terms.

Disclosures. **All authors:** No reported disclosures.

2777. Live-Attenuated Vaccine Against RSV Generates Robust Cellular and Humoral Immune Responses

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Session: 279. Vaccines: Viral Non Influenza
Saturday, October 5, 2019: 12:15 PM

Background: In people over 65, there are on average 177,000 hospitalizations and 14,000 deaths because of respiratory syncytial virus (RSV) each year. Elderly patients infected with RSV can suffer serious infections leading to pneumonia and congestive heart failure. RSV vaccines have failed in the elderly in part because they have been unable to mount a robust cellular immune response.

Methods: RSV-MinL4.0 is a live-attenuated intranasal vaccine candidate that was generated by codon pair deoptimization of the L gene followed by the addition of four stabilizing mutations found via stress passaging. Four African Green Monkeys (AGMs) per group were vaccinated with RSV-MinL4.0 or wild-type (WT) RSV at 2×10^6 PFU, boosted on day 28 and challenged with wild-type (WT) RSV on day 104. Oropharyngeal swabs and tracheal lavage were collected daily and every other day, respectively, to evaluate virus shedding (qPCR) and blood was drawn on days 1, 14, 21, 28, and 49 for antibody titers ($PRNT_{50}$), and PBMC activation (IFNγ ELISPOT with whole inactivated virus).

Results: MinL4.0 was 2 to 3 $\log_{10}$ attenuated when compared with WT RSV in AGMs. Despite the presence of antibodies on day 28, there was a "take" of the boost indicating the potential for this vaccine to be immunogenic in the elderly with pre-existing circulating antibodies (Figure 1A). MinL4.0 led to robust activation of PBMCs comparable to WT RSV (> 2,000 spots per 10^6 total cells, Figure 1B). Shedding of the vaccine and challenge viruses was minimal (data not shown).

Conclusion: MinL4.0 led to robust activation of cellular and humoral immune responses, which are critical for induction of protective immunity in the elderly. Animals were protected from WT challenge. Preliminary data in AGMs with pre-existing antibodies to RSV indicate that circulating antibodies do not prevent vaccine "take," critical for a vaccine targeting sero-positive elderly individuals.

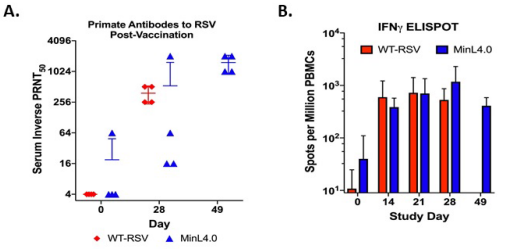

Figure 1: RSV-MinL4.0 generates robust activation of humoral (A) and cellular (B) immunity against RSV

Disclosures. **All authors:** No reported disclosures.

2778. Impact of Reactogenicity on Quality of Life and Physical Functioning in Adults ≥50 Years Receiving Both Doses of the Adjuvanted Recombinant Zoster Vaccine

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Session: 279. Vaccines: Viral Non Influenza
Saturday, October 5, 2019: 12:15 PM

Background: The adjuvanted recombinant zoster vaccine (RZV) is efficacious in preventing herpes zoster in adults ≥ 50 years. The current study investigates whether the vaccinees' quality of life (QoL) and physical functioning (PF) are impacted by local and systemic reactions due to RZV. In a previous report of this phase III, open-label, multicenter study (NCT02979639), overall PF and QoL were not significantly affected by a first RZV dose. [1] Here we report the results from the same study after a second RZV dose and safety results from dose 1 up to study end.

Methods: Adults aged ≥ 50 years were to receive 2 doses of RZV 2 months apart. Changes in mean Short Form health survey (SF-36) PF score between pre- and post-each RZV dose for 7 days, QoL, reactogenicity and safety were assessed.

Results: 401 adults received dose 1 and 391 received dose 2 of RZV. Post-second RZV dose, the reported solicited local symptoms were pain (75.1%), erythema (22.4%) and swelling (13.9%), and the most frequent solicited systemic symptoms were fatigue (46.3%), headache (37.5%) and myalgia (32.9%). Grade 3 solicited symptoms were reported by 7.2% (local) and 11.1% (general) of participants, and 5 (1.2%) participants reported reactogenicity triggering medical attention post-second RZV dose. From first dose up to study end, 14 (3.5%) participants reported 21 serious adverse events, none related to RZV. In days 1–2, post-second RZV dose, a transient, clinically-important decrease in SF-36 PF score (table) was seen in those reporting grade 3 solicited symptoms, which impacted activities such as walking and climbing stairs. Overall, during the 7 days post-second RZV dose, a mean change of –0.4 points was observed from the mean baseline score, indicating the PF was not clinically meaningfully impacted. No overall quality-adjusted-life-year loss was recorded.